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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,548	02/20/2001	Hana Koutnikova	ST00005	5202

29693 7590 12/23/2003

WILEY, REIN & FIELDING, LLP
ATTN: PATENT ADMINISTRATION
1776 K. STREET N.W.
WASHINGTON, DC 20006

EXAMINER	
HAYES, ROBERT CLINTON	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 12/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/785,548	KOUTNIKOVA ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *20 August 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32,33 and 37-62* is/are pending in the application.

4a) Of the above claim(s) *43-52,54-58 and 60-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *32,33,37-42,53 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *32,33,37-62* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. The amendment filed 8/20/03 has been entered.

2. This application contains claims 43-52, 54-58 & 60-62 drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

3. The rejections of claims 32-33 & 59 under 35 U.S.C. 112, second paragraph, for being indefinite, are withdrawn due to the amendment of the claims.

4. The rejection of claims 32-34, 53 & 59 under 35 U.S.C. 102(b) as being anticipated by the Stratagene 1991 Product Catalog is withdrawn due to the amendment of the claims.

5. Applicants' arguments filed 10/20/03 have been considered but are not found persuasive.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) because 37 CFR 1.821 (a)(2)(c-d) states that *each sequence disclosed must appear separately* in the "Sequence listing" and adequately described *in the text of the description* and claims whenever described. See MPEP 2422 & 2431. In other words, it is unclear if SEQ ID NOs: 12 & 42, 13 & 42, 14 & 44, and 15 & 45, respectively, are identical sequences, based on amended Figures 9 & 10. If so, why are identical sequences disclosed; thereby, necessitating a future rejection for duplicative claim limitations in claim 39? In addition, it is unclear how these sequences are a "part of SEQ ID NO:2", as argued in the response. Clarification within the specification is required (e.g., by amending the Figure legend). Note that Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) in order to be fully responsive to this Office Action.

8. Claim 38 stands rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility, for the reasons made of record in Paper No: 13 (mailed 2/20/03).

Applicants argue on page 12 of the response that "the PAP1 protein disclosed has some specific binding effect with regard to parkin", discuss "partial interactions" and reference pages 7 & 9 of the specification. In contrast to Applicants' assertions, no where on pages 7 or 9 is any "specific interaction with parkin" or "an effector region... rendered nonfunctional" discussed or defined. Nor do the claims define such. Thus, the issue remains that "nonfunctional" compounds, as claimed, have no utility, as previously made of record.

9. Claim 38 also stands rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

10. Claims 32-33, 37-42, 53 & 59 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper No: 13 (mailed 2/20/03).

Applicants argue on pages 12-13 of the response that "these claims refer to a peptide *comprising*... part of the amino acid sequence of SEQ ID NO:2". In contrast to Applicants' assertions, no *generic* peptides nor peptides from different species (i.e., nonhuman species) merely *comprising* parts of SEQ ID NO:2 have adequate written description within the specification, and therefore, do not meet the written description requirements under 35 U.S.C. 112, first paragraph for the reasons previously made of record.

Analogous to the situation decided in *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993), "an adequate written description of a DNA [product] requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself". *Fiddes v. Baird*, 30 USPQ2d 1481, 1483 (1993) held that claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class, in which the specification had provided an adequate description of only the bovine sequence. Similarly, only the single human polypeptides species (i.e., human SEQ ID NO: 2) has been described in the instant specification.

Accordingly, as it relates to the required components necessary to practice the claimed method, the court held in *Univ. California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997) that:

"One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is",

and that:

"A description of a genus of cDNAs [products] may be achieved by means of a recitation of a representative number of cDNAs [products], *defined by nucleotide sequence*, failing in the scope of the genus or of a recitation of structural features common to the members of the genus, *which features constitute a substantial portion of the genus* [emphasis added]. This is analogous to enablement of a genus under 112, [first paragraph], by showing the enablement of a representative number of species within the genus. See Angstadt, 537 F.2d at 502-03, 190 USPQ at 218".

In contrast, an invitation for others to discover a representative number of species with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics has not reasonably been provided within the instant specification. Thus, Applicants are not reasonably in possession of the claimed genus of peptides "comprising" part of SEQ ID NO:2. Thus, Applicants' arguments are not on point.

11. Claim 32-33, 37-42, 53 & 59 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the PAP-1 protein of SEQ ID NO:2, does not reasonably provide enablement for any biologically equivalent molecule with no structural and functional characteristics. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record in Paper No: 13 (mailed 2/20/03).

Applicants argue on pages 13-14 of the response that "claim 32 recites the functional language relating to the specific interaction with parkin, which the specification details how to detect and identify". In contrast to Applicants' assertions, no distinguishable and assayable functional language is recited in the current claims, in which the metes and bounds encompassed by the recitation of "*capable of specific interaction* with parkin" is unknown and not disclosed within the instant specification; thereby, preventing the skilled artisan from knowing how to make and use the current invention, as claimed, without requiring undue experimentation to determine such, for the reasons previously made of record. Thus, Applicants' arguments are not persuasive.

12. Claims 32-33, 37-42, 53 & 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is ambiguous what the relative recitation of "capable of *specific* interaction with parkin" entails, in that it is unknown when something becomes "selective", versus no longer being selective.

13. Claims 32-33, 37-42, 53 & 59 stand rejected under 35 U.S.C. 102(e) as being anticipated by Tang et al. (WO 01/46256 A2), for the reasons made of record in Paper No: 13 (mailed 2/20/03).

Applicants argue on pages 14-15 of the response that "no evidence has been provided to necessarily conclude that the polypeptide of Tang possesses the claimed characteristics of claim 32". In contrast to Applicants' assertions, Tang's polypeptide structurally meets the limitations of the currently claims, and therefore, inherently possesses any functional characteristics related to its structure.

Accordingly, it has been established by the courts that a product inherently possesses characteristics of that product (see, e.g., *Ex parte Gray*, 10 USPQ2d, 1922; *In re Best*, 195 USPQ 430), and that

"the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Accordingly, since the issue in the present appeal is whether the prior art factor is identified or patently indistinct from that of the material on appeal, appellants have the burden of showing that inherency is not involved". *Ex parte Gray,* 10 USPQ 2d 1922 (1989); *In re Best,* 195 USPQ 430 (CCPA 1976).

In addition, it is noted that the courts have held that when the prior art product reasonably appears to be the same as that claimed, but differs by process in which it is produced, a rejection of this nature is eminently fair and the burden is upon the appellants to prove, by comparative evidence, a patentable difference (*In re Brown*, 173 USPQ 685 (1972)).

In summary, Tang et al teach an isolated VETRP polypeptide of SEQ ID NO:3 , which is 99.7% identical to the PAP1 protein of SEQ ID NO:2 of the instant invention, and "comprises" 5/9/15 consecutive resides of SEQ ID NO:2 (e.g., pgs. 7, 12, 15-16, 20, 25, 73 & 95; as it relates to claims 32 & 37-42; thereby, inherently also meeting the limitations of a "compound *capable of* specific interaction with parkin"; absent evidence to the contrary. Tang's polypeptide further constitutes a functional part/fragment of the polypeptide of SEQ ID NO:2, as defined by the specification (i.e., as it relates to claims 37 & 38). Composition comprising Tang's polypeptides and pharmaceutically acceptable carriers are disclosed on pages 48 & 97; thereby, also meeting the limitations of claims 53 & 59.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.
December 17, 2003

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600